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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,254	03/27/2001	Scott A. Waldman	TJU-2414	2093

7590

11/27/2002

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/27/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,254	WALDMAN ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-32 and 34-45 is/are pending in the application.
- 4a) Of the above claim(s) 36-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-32, 34, and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Election/Restrictions

The prosecution history indicates that applicant elected group III corresponding claims 25-32 with species B (PCR) and examiner rejoined species B with species A (detection of gene transcription product). Claims 1-24, 28, 32-33 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention; however, it is apparent the examiner examined claims 28, 32-33 drawn to nonelected species in the Office Action mailed on 3/12/2002. Therefore, the species election requirement set forth in the Office Action mailed on 10/30/2001 is withdrawn and all of the three species are examined.

Newly submitted claims 36-45 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 36-45 are drawn to method of determining prognosis of cancer patient while the elected invention is directed to method of cancer diagnosis. The two different inventions have different objectives and requires different samples to be analyzed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 25-32, and 34-45 are pending and claims 25-32, 34, and 35 are examined on merits.

Claim Rejections - 35 USC § 112

Rejection of Claims 25-27 and 29-31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention **is withdrawn** applicant no longer recites the indefinite limitation.

Claim Rejections - 35 USC § 102

Claims 25, 28, 29, 32, and new claims 34 and 35 **remain rejected** for the reasons set forth at page 3 (paragraph # 3) under 35 U.S.C. 102(b) as being anticipated by Silberg et al (1997, Gastroenterology, Vol. 113, pages 478-486).

The claims are interpreted as drawn to method of stomach and esophageal cancer diagnosis by detecting CDX1 translation product.

Applicant argues that Silber et al do not anticipate the amended claims which now recite a limitation that the individual is suspected of having cancer and the claimed method can be used to confirm the suspicion and diagnose the individual as having cancer. However, this argument is not persuasive because Silberg et al teach at page 480 1st column under Tissue Collection that the specimen for the immunological analysis came from patients suspected of having cancer. Note the phrase "initial gross description" and other criteria, which implicitly says the samples examined were came from people suspected of cancer. Further Silberg et al throughout the entire article teach how to use CDX1 as biomarker for stomach and esophageal cancer and sample selection from patient suspected of cancer is inherent. Thus, Silberg et al anticipate the instant claims.

Claim Rejections - 35 USC § 103

Claims 25-27, and 29-31 remain rejected for reasons set forth at page 3 (paragraph # 6) under 35 U.S.C. 103(a) as being unpatentable over Silberg et al (1997, Gastroenterology, Vol. 113, pages 478-486) as applied to claims 25, 28, 29, 32 above, and further in view of Wu et al (1993, IDS, Gastroenterology, Vol. 105, pages 837-44).

The claims are interpreted as drawn to method of stomach and esophageal cancer diagnosis by detecting CDX1 transcription product.

Applicant does not give the reason for the traversal but asserts that the claims are not obvious. However, as stated before in the previous Office Action and restated above, Silberg et al teach method of stomach and esophageal cancer diagnosis by detecting CDX1 using immunological analysis but Silberg et al does not specifically teach a method detecting transcription product. However, Wu et al teach that detecting mRNA of a known protein is a routine procedure at the time the instant application was filed using a variety of techniques including PCR. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to see if detection of CDX1 transcription product is also indicative of cancer since the protein expression came translation of the corresponding transcriptional product and PCR is more sensitive. Note paragraph #6 of page 3 of the previous Office Action.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 112

Claims 25-32, 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite as an active step of the claimed method "identifying the individual as being suspected" of either stomach or esophageal cancer but it is not clear what the metes and bounds are for the limitation. The specification only teaches a method of identifying (diagnosing) an individual by detecting CDX1 expression products and does not teach any other method of identifying an individual suspected of cancer. Does the phrase mean any cancer diagnosis method available in art such as X-ray? Or Does the limitation mean something else?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-32, 34-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, **had possession** of the claimed invention. The amended claims have a new active step of identifying an individual suspected of cancer and the originally filed invention did not have this active step, therefore the active step of claim 25 a) and 29 a) is new matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

November 25, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600